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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: Docket No. 98N-0583
FDA Proposed Rule: Export Notification
And Recordkeeping Requirements

Merck & Co., Inc., is a leading worldwide, human health product company, and as such, Merck imports and exports products on a daily basis, and depends on the efficient flow of material to its domestic and international facilities. Thus, Merck is very much affected by regulations that impact imports and exports. For these reasons, Merck is very interested in and well qualified to comment on this FDA proposed rule on Export Notification and Recordkeeping.

Comments on Proposal

Through enactment of the FDA Export Reform and Enhancement Act of 1996 (Pub. L. No. 104-132), which amended the earlier Drug Export Amendments Act of 1986 (Pub. L. No. 99-960), Congress sought, inter alia, to ease the export of products not approved in the United States. Specifically, the Act was revised to remove restrictions that inhibited the use of US manufacturing facilities to manufacture unapproved products for offshore markets. By removing these unnecessary restrictions, Congress sought to retain jobs in the United States that might otherwise be lost to offshore manufacturing.

The regulations in the proposed rule are burdensome and contrary to both the letter and spirit of both the 1986 and 1996 drug export act amendments. Merck considers many of the reporting requirements to be a step in the wrong direction relative to the enhancements of the 1996 Export Reform Act. The proposed rule if implemented will hamper the flow of materials out of the US, reducing the ability of US companies to compete in the global market. We therefore request the FDA to consider the specific comments that follow and to reflect on the initial intent of the 1986 and 1996 drug export act amendments in revising the proposed rule.

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Specific Comments

I. Proposed 21 C.F.R. §1.101(b)(2) – Recordkeeping Requirements

FDA's proposed §1.101(b)(2) would require a letter from an appropriate government agency, department or body stating that the subject product has marketing approval from the destination country or does not conflict with that country's laws. This proposed regulation is unduly burdensome, and neither required by nor authorized by the export legislation. Obtaining such confirmatory letters from foreign officials creates a substantial administrative burden and can cause significant delay. While the export legislation permits export if the product is in accordance with the laws of the destination country, Congress did not require exporters to obtain any documentary proof from foreign officials. In many instances, the foreign government may not have provided any express marketing approval – and under such circumstances it is unrealistic to expect that the type of documentary proof proposed by the FDA may be obtained without both significant burden and delay, if at all.

Congress has nowhere asserted or implied that the advice of counsel or other corporate due diligence with respect to documenting compliance with the destination country's laws is inadequate. Yet FDA, in proposed §1.101(b)(2), has inexplicably foreclosed this very effective yet pragmatic and efficient method of ensuring compliance with the requirements of this export legislation.

§1.101(b)(2) seeks to reintroduce the very type of bureaucratic procedures that Congress intended to eliminate through the passage of this legislation. This proposed rule, if allowed to stand, will impede the export of products at best and may ultimately prevent the export of certain products.

II. Proposed 21 C.F.R. §1.101(d)(1)(iv) – Notification Requirements

FDCA §802(g) requires that, for exports to countries not listed under FDCA §802(b)(1), the exporter must provide a "simple notification" to FDA identifying both the product and the destination country. By contrast, FDCA §802(g) requires that, for exports to countries that are listed under FDCA §802(b)(1), the simple notification need identify only the exported product. Congress has been clear and unequivocal with respect to these requirements.

FDA's proposed §1.101(d)(1), however, would require that, for listed countries under FDCA §802(b)(1), the simple notification identify not only the product, but also the importing country.

This proposed rule is plainly contrary to the letter of both the 1986 and 1996 legislative amendments. FDA's claimed justification that the requirement is necessary to facilitate FDA's responsibilities is ineffectual given the clear lack of supporting statutory authority. Further, the proposed rule violates the spirit of the legislative amendments inasmuch as exporters would be required to send multiple notices as products were exported to additional listed countries. Congress' "simple notification" would become significantly complicated by the proposed rule, which is contrary to Congress' intent to ease the export of products not approved in the United States.

We trust that these comments will be considered in further development of the proposed rule. We strongly recommend that the rule be revised to bring it in line with Congress' intent in enacting the 1986 and 1996 export amendments.

Sincerely,

Dennis M. Erb

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